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10/087,014	03/01/2002	Henrik Hansen	12013/59301	2646

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EXAMINER	
TSOY, ELENA	

ART UNIT	PAPER NUMBER
1762	

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/087,014	HANSEN ET AL.	
	Examiner	Art Unit	
	Elena Tsoy	1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16,18,19,25-29,31,33,35,37 and 39-45* is/are pending in the application.

4a) Of the above claim(s) *29 and 40-45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16,18,19,25-28,31,33,35,37 and 39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 22, 2006 has been entered.

Response to Amendment

2. Amendment filed on September 22, 2006 has been entered. Claims 30, 32, 34, 36, and 38 have been cancelled. New claims 40-45 have been added. Claims 1-16, 18-19, 25-29, 31, 33, 35, 37, and 39-45 are pending in the application.

Election/Restrictions

3. Newly submitted claims 40-45, and amended claim 29 are directed to an inventions that is independent or distinct from the invention originally claimed for the following reasons: specification as filed shows that (i) **spray nozzles** (See Fig. 6; P29, P31) positioned either on the wall of the drum, as required by new claims 40-41, or on the bottom of the drum, as required by new claims 42-43, (ii) **perforations** in the wall of the drum (See Fig. 5; P30-32) of amended claim 29 are embodiments that are *alternative* to the originally presented channel (See Fig. 7; P33). Note that a dual use channel of claim 44 is one of features of a part of the embodiment (i), and a removable lid of claim 45 is one of features of the embodiment (ii).

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, **amended claim 29** and **new claims 40-45** are **withdrawn** from consideration as being directed to inventions that are independent or distinct from the invention originally claimed.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Rejection of claims 1, 2, 12, 13 under 35 U.S.C. 103(a) as being unpatentable over Vickery (US 3,991,750) in view of Lucke (5,302,201) has been withdrawn due to amendment.

6. Rejection of claim 3 under 35 U.S.C. 103(a) as being unpatentable over Vickery (US 3,991,750) in view of Lucke (5,302,201), further in view of Yalkowsky (US 4,489,026) has been withdrawn due to amendment.

7. Rejection of claim 4 under 35 U.S.C. 103(a) as being unpatentable over Vickery (US 3,991,750) in view of Lucke (5,302,201), further in view of Forster (US 4,581,242) has been withdrawn due to amendment.

8. Rejection of claims 7, and 9-11 under 35 U.S.C. 103(a) as being unpatentable over Vickery (US 3,991,750) in view of Lucke (5,302,201), further in view of Dunajtschik (US 4,586,457) has been withdrawn due to amendment.

9. Rejection of claim 19 under 35 U.S.C. 103(a) as being unpatentable over Vickery (US 3,991,750) in view of Lucke (5,302,201), further in view of Fernandez et al (US 3,696,188) has been withdrawn due to amendment.

10. Claims 1-3, 12, 13, 18, 25-28, 31, 33, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roorda et al (US 20040261698) in view of Lucke (5,302,201).

Roorda et al disclose a method of coating stents (See P16) for the delivery of therapeutic (See P21) comprising: placing stents into a rotatable pan 204 including a drum, tumbling the stents by rotating the drum about a longitudinal axis of the drum (obviously stents are free to strike the bottom or the wall of the drum) (See Fig. 2; P17), spraying a therapeutic in a solvent carrier over the tumbling stents (See P18); and removing the solvent using hot air of 15-200 ^{0}C (drying) (See P19).

Roorda et al fail to teach that that the therapeutic is sprayed by moving it through a channel positioned in the drum and containing a plurality of orifices (Claim 1); the drum has a plurality of orifices in the wall (Claims 12 and 13).

Lucke teaches that coating cores in rotary drums containing a plurality of orifices 51 in the wall, where a pharmaceutical coating material is applied (See column 4, lines 21-22) by moving the coating materials through a carrier (channel) 54 positioned in the drum and having a plurality of spraying nozzles (orifices) 53, spraying the coating materials through the nozzles 53 (See Fig. 4; column 7, lines 30-38) and the applied coating is dried by blowing a gas, allows to achieve high quality of coated cores (See column 4, lines 34-35).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have coated cores of Roorda et al using a rotary drum of Lucke containing a plurality of orifices, where a pharmaceutical coating material is applied by moving the coating materials through a carrier positioned in the drum and having a plurality of spraying nozzles, and spraying the coating materials through the nozzles, and the applied coating is dried by blowing a gas with the expectation of providing the desired high quality of coated cores, as taught by Lucke.

As to claims 3 and 26, Roorda et al fail to teach that inert gas is used instead of air.

It is well known in the art that inert gas should be used in case a bioactive coating is sensitive to air.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used inert gas in Roorda et al with the expectation of providing the desired high quality bioactive coating if a bioactive coating is sensitive to air.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used inert gas in Roorda et al in view of Forster with the expectation of providing the desired high quality bioactive coating if a bioactive coating is sensitive to air.

As to claims 28, blowing of air or gas does not continue indefinitely and thus is "periodic".

11. Claims 12, 13, 25-28, 33, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roorda et al in view of Forster (US 4,581,242).

Roorda et al are applied here for the same reasons as above. Roorda et al fail to teach that implants are suspended above an internal surface of the drum.

Forster teaches blowing air or gas up through the bed of objects in a side vented coating pan (i.e. having a plurality of orifices in the wall as claimed) allows drying the objects at all levels (i.e. suspending the medical implants) provides defect-free coatings as they are held aloft (See column 1, lines 18-30, 42-50).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified a method of Roorda et al to blow air up through the articles in the coating pan to suspend the medical implants with the expectation of providing the desired defect-free coatings as they are held aloft, as taught by Forster.

As to claim 26, It is well known in the art that inert gas should be used in case a bioactive coating is sensitive to air.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used inert gas in Roorda et al in view of Forster with the expectation of providing the desired high quality bioactive coating if a bioactive coating is sensitive to air.

As to claims 28, blowing of air or gas does not continue indefinitely and thus is "periodic".

12. Claims 1-4, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roorda et al in view of Forster, further in view of Lucke.

Roorda et al in view of Forster fail to teach that the therapeutic is sprayed by moving it through a channel positioned in the drum and containing a plurality of orifices (Claims 1, 29)

Lucke teaches that coating implants in rotary drums containing a plurality of orifices 51 in the wall, where a pharmaceutical coating material is applied (See column 4, lines 21-22) by moving the coating materials through a carrier (channel) 54 positioned in the drum and having a plurality of spraying nozzles (orifices) 53, spraying the coating materials through the nozzles 53 (See Fig. 4; column 7, lines 30-38) and the applied coating is dried by blowing a gas, allows to achieve high quality of coated cores (See column 4, lines 34-35).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have sprayed a coating material in Roorda et al in view of Forster by moving the coating material through a carrier positioned in the drum and having a plurality of spraying

nozzles with the expectation of providing the desired high quality of coatings because Lucke teaches that coating implants in rotary drums containing a plurality of orifices in the wall, where a pharmaceutical coating material is applied by moving the coating materials through a carrier (channel) positioned in the drum and having a plurality of spraying nozzles (orifices), spraying the coating materials through the nozzles and the applied coating is dried by blowing a gas, allows to achieve high quality of coated implants.

13. Claims 5, 6, 8, 14-16, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roorda et al in view of Forster, further in view of Schwartz et al (US 6,607,598).

Roorda et al in view of Forster are applied here for the same reasons as above. Roorda et al in view of Forster fail to teach that and the medical implant has a masking material on at least one surface (Claim 5).

Schwartz et al state that *masking* techniques are **known** in the art for partial coating of stents to result in coating of predetermined stent segments (See column 11, line 67; column 12, lines 1-2).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used known masking techniques for coating stents in Roorda et al in view of Forster with the expectation of providing the desired coating of predetermined segments of the stents.

As to claim 6, Claim 6 is rejected because collection of Roorda et al in view of Forster any fluid inherently requires a reservoir.

As to claim 8, Schwarz '598 teaches multiple layers (col. 7, line 40).

14. Claims 7, 9-11, 37, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roorda et al in view of Forster, further in view of Dunajtschik (US 4,586,457).

Roorda et al in view of Forster are applied here for the same reasons as above. Roorda et al in view of Forster fail to teach that air is re-circulated (Claims 7, 9).

Dunajtschik teaches that it is possible in principle to completely seal the inner space of the coating drum 2 against the atmosphere, so that either directly or within the surrounding housing the process can run with recirculated air (See column 7, lines 14-26).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have completely sealed the inner space of the coating drum in Roorda et al in view

of Forster against the atmosphere, so that either directly or within the surrounding housing the process can run with recirculated air with the expectation of providing the desired isolation of operation, as taught by Dunajtschik.

15. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Roorda et al in view of Forster, further in view of Fernandez et al (US 3,696,188).

Roorda et al in view of Forster are applied here for the same reasons as above. Roorda et al in view of Forster fail to teach that cores coated with a first and a second bioactive coating layers.

Fernandez et al teach that inert cores can be coated with multiple bioactive coating layers depending on intended use of a final product (See column 3, lines 5-20).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have coated inert cores in Roorda et al in view of Forster with multiple bioactive coating layers depending on intended use of a final product, as taught by Fernandez et al.

As to recycling, while the references fail to specifically teach recycling the therapeutic agent, Examiner notes that pharmaceuticals are very expensive. In a spray coating operation, a large quantity of coating material is "lost" and misses its targets. It is Examiner's position that one of ordinary skill in the art would provide a recycling operation to recover the lost pharmaceuticals to be used in a later coating operation so as to maximize manufacturing profits.

Response to Arguments

16. Applicant's arguments with respect to claims 1-16, 18, 19, 25-28 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elena Tsoy whose telephone number is 571-272-1429. The examiner can normally be reached on Monday-Thursday, 9:00AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elena Tsoy
Primary Examiner
Art Unit 1762

October 10, 2006

ELENA TSOY
PRIMARY EXAMINER